UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

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| LINDA STANGER and, | ) | |
| RICHARD STANGER | ) | |
| Plaintiffs, | ) | |
| | ) | |
| vs. | ) | Case No. 4:04CV839 HEA |
| | ) | |
| SMITH & NEPHEW, INC., et al., | ) | |
| | ) | |
| Defendants. | ) | |

**MEMORANDUM AND ORDER**

This matter is before the Court on defendant Thomas Satterly, Jr.'s (Satterly) Motion for Summary Judgment, [Doc. No. 68], plaintiffs' Motion for Partial Summary Judgment, [Doc. No. 90], defendants Smith & Nephew, Inc., (S&N), Larry Gross and Larry Gross & Associates, Inc., (Gross), Ted Toler and Ted Toler & Associates, Inc.'s (Toler), Motions for Summary Judgment, [Doc. No.'s 97, 98 and 99], plaintiffs' Motion for Partial Summary Judgment on Negligent Failure to Warn, [Doc. No. 112], and plaintiffs' Motion for Partial Summary Judgment on Strict Liability Product Defect against Defendant Smith & Nephew, [Doc. No. 113]. For the reasons set forth below, defendants S&N, Toler-Gross' Motions for Summary Judgment are granted in part and denied in part; plaintiffs' Motion for Partial Summary Judgment on their Strict Liability Product Defect Claim is denied; plaintiffs' Motion for Summary Judgment on their Negligent Failure to Warn Claim

is granted; plaintiffs' Motion for Partial Summary Judgment on the Learned Intermediary Defense, is granted and defendant Satterly's Motion for Summary Judgment is granted.

## Introduction

Plaintiffs initiated this action based on allegations of design, manufacturing and/or marketing defects relating to S&N's Genesis I medium left 15 mm articular insert (the tibial insert) which was implanted in plaintiff Linda Stanger. Plaintiffs contend that the Ultra-High Molecular Weight Polyethylene (UHMWPE) insert was defective and unreasonably dangerous because it was sterilized using gamma irradiation in air. Gamma irradiation in air causes oxidation of UHMWPE. The greater the length of time for exposure to the air of the gamma-irradiated UHMWPE, the more it oxidizes. Due to the length of time the insert was exposed to air, the insert failed eight months after implantation into Plaintiff Linda. Plaintiff Linda was required to undergo revision surgery. Plaintiffs seek compensatory and exemplary damages from defendants S&N, Toler and Gross and compensatory damages from defendant Satterly based on theories of strict liability, negligence, breach of implied warranties, and misrepresentation. Plaintiff Richard Stanger seeks recovery for loss of consortium and services of his wife Linda.

## Facts and Background

S&N manufactured and marketed artificial knee joints known by the brand name, Genesis I. The Genesis I has several components. One of the components is a UHMWPE 'tibial insert.' This type of artificial knee device was implanted into Linda Stanger on April 15, 2002.

On March 12, 1991, Smith & Nephew Richards, Inc., the predecessor to S&N, manufactured and packaged a Genesis I medium left 15 mm articular insert bearing catalog number 724519, lot number 1A09964. According to plaintiffs' expert William H. Damaska, in 1991, the tibial insert was appropriately branded and labeled. According to plaintiffs' expert Robert Schiff, in 1991, the FDA did to require a serial number on the tibial insert that would allow the tibial insert to be traced. The tibial insert was not taken out of its original packaging anytime prior to April 15, 2002.

On March 24, 1991,[1] the tibial insert was sterilized using gamma irradiation in air. In 1991, gamma sterilization of these type tibial inserts was virtually the universal industry practice and methodology in the United States.[2] In 1991, it had

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[1] Plaintiff submits that the sterilization occurred on March 2, 1991 and defendants admit same, however, defendant's statement of uncontested facts state that the sterilization occurred on March 24, 1991, and plaintiffs did not dispute this date. It appears that the March 24, 1991 date is the correct date in light of the date of manufacture being March 12, 1991.

[2] In 1994, S&N converted from air packaging gamma sterilization for UHMWPE devices to inert gas (ethylene oxide) packaging. This action was initiated based on evidence this process would substantially prevent degradation to UHMWPE devices as a result of the sterilization process.

not been determined that there was a shelf life on gamma irradiated tibial inserts. By 1996, information became available that problems regarding gamma sterilized polyethylene with a shelf life in excess of five years causes the tibial insert to lose its intended strength and makes it unsuitable for implantation. Gamma sterilization, in and of itself is not immediately detrimental. However, this sterilization process initiates long-term chemical changes within the polyethylene, including oxidation. A consequence of oxidation is that, over time, the material properties are reduced. The chemical changes that take place in UHMWPE are a function of time after sterilization, and the time frame between sterilization and implantation is referred to as the "shelf life" of the component. The oxidation of the tibial insert continued while it was in its packaging. The oxidation of the tibial insert caused delamination. The packaging insert for the tibial insert did not warn about the dangers of gamma sterilization in air and shelf aging. Within the years 1994-1997 S&N initiated efforts to remove gamma sterilized components from the field due to the likelihood of failure.

According to plaintiffs' expert William H. Damaska, the tibial insert was not misbranded or mislabeled in 1991 because it was not until 1996 that there was a body of evidence indicating the tibial insert was not safe and S&N and the industry in general became aware of the information. Further, Damaska does not believe the FDA required the removal of gamma sterilized polyethylene products from the

market. Furthermore, he does not believe the FDA took affirmative action to have gamma sterilized polyethylene products removed from the market.

S&N's records establish that on April 2, 1991, a Genesis I medium left 15 mm articular insert, catalog number 72419, lot number 1A009964 was delivered to Larry Gross, an independent sales representative of S&N. This insert was sold to Phelps County Regional Medical Center on May 6, 1991. There is no record of any other instance of the sale of a Genesis I medium left 15 mm articular insert to Phelps County Regional Medical Center.

During the time period from 1989 through 1997, almost all of Phelps County Regional Medical Center's medical device inventory was owned by the Hospital. Phelps County Regional Medical Center has no records of the tibial insert implanted into plaintiff, in that all records prior to the conversion of its record keeping system in 1993 were destroyed.

On April 15, 2002, plaintiff Linda Stanger underwent total arthroplasty at the Phelps County Regional Medical Center. Defendant Satterly implanted S&N's Genesis I artificial knee, which included the tibial insert. Eight months later, on December 9, 2002, Linda was required to undergo revision surgery to replace the insert.

Sometime within the years 1994-1997, S&N developed and executed a plan to exchange tibial inserts that were sterilized in air and shelf aged longer than 5

years. S&N undertook to advise distributors to exchange old UHMWPE product for new ethylene oxide product.

## Discussion

### Summary Judgment Standard

The standards for summary judgment are well settled. Summary judgment is appropriate when there exists no genuine issue as to any material fact. *Celotex Corp. v. Citrate*, 477 U.S. 317, 322 (1986). The moving party has the burden to establish both the absence of a genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Once the moving party has met this burden, the nonmoving party may not rest on the allegations in his pleadings but by affidavit or other evidence must set forth specific facts showing that a genuine issue of material fact exists. Fed.R.Civ.P. 56(e); *Anderson* 477 U.S. at 256; *Krenik v. Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). "'Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.' *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)." *Hitt v. Harsco Corp.*, 356 F.3d 920, 923 (8th Cir. 2004). To survive a motion for summary judgment, the "nonmoving party must 'substantiate his allegations with sufficient probative evidence [that] would permit a finding in [his] favor based on more than mere speculation, conjecture, or fantasy.' *Wilson v. Int'l Bus. Machs.*

*Corp.*, 62 F.3d 237, 241 (8th Cir. 1995)(quotation omitted)." *Putman v. Unity Health System*, 348 F.3d 732, 733-34 (8th Cir. 2003). "[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 323.

**Strict Liability Product Defect**

Pending before the Court are defendants' motion for summary judgment and plaintiffs' motion for partial summary judgment on plaintiffs' strict liability product defect claim. Defendants argue that they are entitled to judgment because the tibial insert was not defective at the time it entered the stream of commerce; plaintiffs argue that the product was defective at the time it was manufactured and further argue that there are issues of material fact as to when the tibial insert was sold.

The Court's jurisdiction over this matter is based upon diversity of citizenship. In this regard, neither party objects to the application of Missouri law to the products liability issues in this case. "In *Keener v. Dayton Electric Manufacturing Company*, 445 S.W.2d 362, 364 (Mo.1969), Missouri 'adopted the rule of strict liability in defective product claims as defined in Restatement (Second) of Torts § 402A.' *Gramex Corp. v. Green Supply, Inc.*, 89 S.W.3d 432, 438-39 (Mo. banc 2002), citing *Lippard v. Houdaille Indus., Inc.*, 715 S.W.2d 491, 492 (Mo. banc 1986), and *Blevins v. Cushman*, 551 S.W.2d 602, 606 (Mo. banc 1977).

This rule

causes a person who sells a product 'in a defective condition [un]reasonably dangerous to the user or consumer' to be liable to the ultimate user or consumer for any harm caused by use of the product if '(a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.'

*Gramex*, 89 S.W.3d at 439, quoting *Keener*, 445 S.W.2d at 364." *Crump v. Versa Products, Inc.*, 400 F.3d 1104, 1107 (8th Cir. 2005); "Under Missouri law, to prevail in a products liability action under a theory of defective design, an injured plaintiff must establish that 1) defendant sold the product in the course of its business; 2) the product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use; 3) the product was used in a manner reasonably anticipated; and 4) plaintiff was injured as a direct result of such defective condition as existed when the product was sold. *Jaurequi v. John Deere Co.*, 971 F.Supp. 416, 422 (E.D.Mo.1997); *Waggoner by Waggoner v. Mercedes Benz of North Am., Inc.*, 879 S.W.2d 692, 694 (Mo.App.E.D.1994)." *Pillow v. General Motors Corp.* 184 F.R.D. 304 (E.D.Mo.,1998). See also, *Boyer v. Bandag, Inc.* 943 S.W.2d 760, 763 (Mo.App. E.D. 1997). (Missouri courts have consistently held that a manufacturer's liability is predicated upon the dangerous nature of the product at the time it leaves the hands of the manufacturer. *Keener v.*

*Dayton Electric Manufacturing Company*, supra at [6]; *Bailey v. Innovative Management & Investment, Inc.*, 916 S.W.2d 805 (Mo.App.1995)[4,5]; *Gabler, supra* at [8-10]; *Klein v. General Electric Company,* 714 S.W.2d 896 (Mo.App.1986)[2]; *Lewis v. Envirotech Corp.*, 674 S.W.2d 105 (Mo.App.1984) [1]; *Racer v. Utterman*, 629 S.W.2d 387 (Mo.App.1981)[11]); *Jasinski v. Ford Motor Co.*, 824 S.W.2d 454, 455 (Mo.App. E.D. 1992). (Thus, in order to recover under their theory of a defectively designed product, plaintiffs must establish the following: (1) defendant sold the product in the course of its business; (2) the product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.); *Leonard v. Bunton Co.*, 925 F.Supp. 637, 641-42 (E.D. Mo 1996) (Under Missouri law, in order to recover under the theory of strict liability for defective design, a plaintiff must demonstrate that the product, as designed, is unreasonably dangerous and therefore defective, and that the demonstrated design defect caused his/her injuries. *Jones v. Ryobi, Ltd.*, 37 F.3d 423, 425 (8th Cir.1994); *Sutherland*, at 1290; *Stinson*, at 431. Specifically, the plaintiff must establish: 1) the defendant sold the product in the course of its business; 2) the product was then in a defective condition unreasonably dangerous when put into a reasonably anticipated use; 3) the product was used in a manner

reasonably anticipated; and 4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold. *Pree*, at 865 citing *Linegar v. Armour of Am., Inc.*, 909 F.2d 1150, 1152 (8th Cir.1990). It is, likewise, well-established under Missouri law that in order for a plaintiff to recover on a theory of strict liability for defective design, a plaintiff must prove that his or her *injury* was the *direct* result of a defect that existed when the product was sold. *Jones v. Ryobi*, at 425.); *Sperry v. Bauermeister, Inc.* 786 F.Supp. 1512, 1516 . (E.D.Mo. 1992). ("Under the Missouri law of strict liability in tort for defective design, in order to establish liability of the seller or manufacturer, a plaintiff must demonstrate that 1) the product was defective and dangerous when put to a use reasonably anticipated by the manufacturer and 2) the plaintiff sustained injury or damage as a direct result of the defect. *Lewis v. Envirotech Corp.*, 674 S.W.2d 105, 110 (Mo.App.1984). The plaintiff has the burden to demonstrate the defect existed when the product left the control of the manufacturer and entered the stream of commerce. *Lewis*, at 110. Consequently, a supplier is not liable when it delivers a product in a safe condition but subsequent mishandling renders the product defective. *Donahue v. Phillips Petro.*, 866 F.2d 1008, 1010 (8th Cir.1989) citing *Porter v. C.A. Dawson & Co.*, 703 F.2d 290 (8th Cir.1983) and *Williams v. Ford Motor Co.*, 494 S.W.2d 678 (Mo.App.1973)").

The record now before the Court establishes that the tibial insert was unfit at the time it was implanted into Linda. This fact alone, however, does not establish strict liability. Although plaintiffs argue that the insert was defective from inception because it was susceptible to delamination over time, this argument ignores Plaintiffs' own experts' reports which establish that the cause of the failure of the insert was not the mere fact of gamma sterilization alone.[3] Coupled with this fact is the further fact of the insert's shelf life. In order for any danger to occur from the insert because of delamination, the insert must have a shelf life, that is, it must be stored, in excess of five years or more. Had the insert been implanted immediately or within five years from sterilization, there would be no delamination. Plaintiffs' reliance on *Dorman v. Bridgestone/Firestone, Inc.*, 992 S.W.2d 231 (Mo.App. E.D. 1999) is misplaced because the design defect in *Dorman* caused rust to immediately form as soon as the product was put to use. Thus, there was no point at which the *Dorman* product was fit for its intended use. In this case, however, at the time the insert was placed in the stream of commerce, *i.e.*, at the time of sale, there is absolutely *no* evidence to establish that it was in a defective condition; there would have been no delamination had the product at issue been used prior to the

[3] Plaintiffs' submission of additional affidavits from their experts do not controvert the reports. Although Dr. Schurman's affidavit avers that the failure was due to "excessive delamination," the record and his report establish that the delamination was caused by the length of time this particular insert sat without being used.

point at which the shelf life begins to break down the insert. Thus, at the time S&N placed the insert into the stream of commerce in 1991, it was not unreasonably dangerous. Under Missouri law, Plaintiffs cannot, therefore establish that the tibial insert was defective at the time S&N sold- placed it into the stream of commerce, as it were- to Phelps County Regional Health Center.

Plaintiffs also argue that a genuine issue exists regarding when the insert was sold. This argument relies on pure speculation and conjecture. While defendants' tibial inserts do not include a specific serial number or other tracking mechanism for the insert, defendants have produced records which establish that only one Genesis I tibial insert with the catalog number 724519, lot number 1A09964, ever delivered to Phelps County Regional Medical Center was sold on May 6, 1991. Although Phelps County employees testified that there was no record of the hospital ever purchasing this insert, the record also establishes that the hospital has destroyed its pre-1993 records. Thus the fact that the hospital has no such record fails to controvert defendants' records showing the sale. Plaintiffs have failed to produce any evidence other than defendants' sale date. The arguments that the insert "could have" been brought by a sales representative on the day of Linda's surgery or that it could have been a special order prior to surgery are unsupported by any admissible evidence and are based solely on speculation and conjecture. The record before the Court establishes that the sale of the insert occurred on May 6, 1991.

Because the tibial insert was placed in the stream of commerce, *i.e.*, was sold to Phelps County Regional Health Center on May 6, 1991, and at that time was not unreasonably dangerous, defendants are entitled to judgment as a matter of law on plaintiffs' design defect claim.

**Strict Liability Failure to Warn**

Defendants also move for summary judgment on plaintiffs' strict liability failure to warn claim. Plaintiffs admit that defendants are correct that the "State of the Art" is a complete defense for strict liability failure to warn. R.S.Mo. § 537.764.[4] Plaintiffs however, once again argue that there is a dispute as to the date

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[4] This Section provides:

**537.764. State of the art, defined--affirmative defense in cases of strict liability for failure to warn--burden of proof on party asserting defense-- action for negligence, when**

1. As used in this section, **"state of the art"** means that the dangerous nature of the product was not known and could not reasonably be discovered at the time the product was placed into the stream of commerce.

2. The state of the art shall be a complete defense and relevant evidence only in an action based upon strict liability for failure to warn of the dangerous condition of a product. This defense shall be pleaded as an affirmative defense and the party asserting it shall have the burden of proof.

3. Nothing in this section shall be construed as limiting the rights of an injured party to maintain an action for negligence whenever such a cause of action would otherwise exist.

4. This section shall not be construed to permit or prohibit evidence of feasibility in products liability claims.

the insert was sold. This argument, as previously discussed, is unavailing for plaintiffs. The record clearly establishes that S & N sold the tibial insert to Phelps County Regional Medical Center on May 6, 1991. As such, defendants are entitled to summary judgment on this claim. At the time of sale, gamma sterilization was virtually universal *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 537 (7th Cir. 2005) ("[A]t the time of the subject I/B Knee implant's manufacture (1991), it was virtually universal industry practice to sterilize such implants by gamma irradiation in air. Indeed, no manufacturer at that time employed any of [plaintiff's expert's] proffered methods, and [the expert] has cited no contemporary articles counseling the use of such methods.") Plaintiffs acknowledge that if the device was sold after the mid-1990s, defendants would have had knowledge of the "defect" and would not be entitled to rely on this defense. However, because the record establishes that the device was sold in 1991, defendants are entitled to the "State of the Art" defense on plaintiffs' strict liability failure to warn.

**Negligence**

Plaintiffs allege that defendants were negligent in failing to exercise reasonable and ordinary care in the design, manufacture, testing, marketing, promoting, advertising, sale, supply and/or distribution of the insert into the stream of commerce. They further allege that Gross and Toler were negligent in the marketing, promoting, advertising, sale, supply and/or distribution of the insert into

the stream of commerce. The Second Amended Complaint also alleges that defendants were negligent in failing to warn Linda and/or her physicians of the dangers associated with the insert, in failing to adequately test the insert, and in failing to remove it from the market before it was ever implanted into Linda, given their knowledge of the unreasonably dangerous and defective design and manufacture of the insert. Plaintiffs claim that defendants misrepresented any claimed benefits for the insert without accurately stating the true frequency, nature and extent of the risks associated with the insert's use.

**Negligence in Design and Manufacture and in Marketing, Promoting, Advertising, Selling, Distributing, and/or Placing the Insert into the Stream of Commerce**

As previously discussed, at the time the insert was placed in the stream of commerce in 1991, none of the defendants knew nor reasonably should have known that the insert would break down after an extended shelf life. As such, defendants are entitled to summary judgment on plaintiffs' negligence design claims.

> The current negligence standard in Missouri sets forth that a seller of a product who neither knows nor has reason to know the product is dangerous is not liable in a negligence action for harm caused by the product's dangerous condition because of the seller's failure to discover the danger by an inspection or test of the product before selling it. Restatement (Second) of Torts, section 402 (1965); See also, *Welkener v. Kirkwood Drug Store Co.*, 734 S.W.2d 233, 241 (Mo.App.1987); *Willey v. Fyrogas Co.*, 363 Mo. 406, 251 S.W.2d 635, 639 (1952).

*Dorman v. Bridgestone/Firestone, Inc.*, 992 S.W.2d 231, 239 (Mo.App. 1999).

**Negligent Failure to Warn**

Plaintiffs move for summary judgment on the negligent failure to warn based on several theories. Likewise, defendants argue they are entitled to Summary Judgment on this issue because they owed no duty to warn of any alleged defect after the sale of the insert in 1991.

The Court agrees with defendants that under Missouri law, there is no cause of action for negligent recall.

> [T]here is no indication, by case law, statue, or otherwise, that the Missouri Supreme Court would create a common law duty to recall... Moreover, in light of the fact that there is no recognized duty to recall, we hold such a duty cannot arise as a result of [defendant's] voluntary undertaking to recall certain of its [products]. Furthermore, Missouri case law on failure to warn suggests that, in order for appellants to pursue a negligent recall claim, the defect in the [product] would have had to exist at the time the product left [defendant's] control and entered the stream of commerce.

*Horstmyer v. Black & Decker (US) Inc.*, 151 F.3d 765, 773-74 (8th Cir. 1998). Absent a mandated recall by a governmental agency, defendants had no duty to recall the tibial insert. *Id.*

Although plaintiffs characterize their cause of action as one for "voluntary undertaking" in challenging defendants' actions with respect to the replacement of certain Genesis I artificial knees, these actions are, under any terminology, a

voluntary recall, *i.e.* the removal of an allegedly defective product. Plaintiffs' labeling of the recall as a "voluntary undertaking" does not transform the allegedly negligent recall into a viable cause of action.

**Post-Sale Duty to Warn**

Plaintiffs argue that they are entitled to summary judgment based on a continuous duty to warn; defendants contend they are entitled to summary judgment on this issue because Missouri does not recognize a cause of action for post-sale failure to warn. While the Court agrees with defendants that there is no strong indication that the Missouri Supreme Court would adopt the RESTATEMENT (THIRD) OF TORTS, See, *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 65, (Mo. banc 1999); *Uxa ex rel. Uxa v. Marconi*, 128 S.W.3d 121, 130 (Mo.App. 2003), which imposes a continuous duty to warn, the Court agrees with plaintiffs that S&N owed a duty to warn post-sale of the insert because of its particular nature as a medical devise.

The Eighth Circuit has examined a manufacturer's duty post-sale with respect to prescription drugs.

> We examine the appellant's contentions in the light of the continuous duty cast upon the manufacturer of an ethical drug to warn physicians of the dangers incident to prescribing the drug, to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical profession of any additional side effects discovered from its use.

*Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 922 (8th Cir. 1970), citing *O'Hare v. Merck & Co*, 381 F.2d 286, 290-91 (8th Cir. 1967); *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 95 (Mo. 1969); and *Krug v. Sterling Drug, Inc*. 416 S.W.2d 143 (Mo. 1967).(Emphasis added). "The manufacturer of a prescription drug to be administered to human beings is 'held to the skill of an expert in that particular business' and 'to an expert's knowledge of the arts, materials and processes,' and is bound to keep reasonably abreast of scientific knowledge and discoveries concerning his field and, of course, is deemed to possess whatever knowledge is thereby imparted.' *Krug v. Sterling Drug, Inc., supra*, 416 S.W.2d l.c. 152(8). *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623Mo. 1968. This duty also applies to medical devices. See *Kirsch v. Picker International, Inc.* 753 F.2d 670, 671 (8th Cir. 1985).

Defendant's casual dismissal of this authority as inapplicable because these cases address the "ongoing sale' of the drugs fails to relieve it of its duty. Nothing in these cases limits a manufacturer's post-sale duty to warn of dangers associated with drugs and/or medical devices based on "continous sale." The duty, rather is imposed on manufactures by reason of the fact that they are considered "experts" and are required to remain abreast of developments as they become available to them.

The record establishes that S&N failed to notify either Phelps County Regional Medical Center or defendant Satterly of the risk of delamination of the tibial insert after a 5 year shelf life. This is the exact type of risk for which the duty exists. Accordingly, plaintiffs are entitled to summary judgment on their negligent failure to warn claim based on S & N's continuous duty to warn.

**Negligent Misrepresentation**

Plaintiffs claim that defendants were negligent in promoting, overstating and misrepresenting any claimed benefits of the tibial insert.

> To state a claim for negligent misrepresentation, [P]laintiffs must plead facts that establish: (1) speaker supplied information in the course of his business or because of some other pecuniary interest; (2) due to speaker's failure to exercise reasonable care or competence in obtaining or communicating this information, the information was false; (3) speaker intentionally provided the information for the guidance of a limited group of persons in a particular business transaction; (4) listener justifiably relied on the information; and (5) that as a result of listener's reliance on the statement, he/she suffered a pecuniary loss. *Miller v. Big River Concrete, L.L.C.*, 14 S.W.3d 129, 133 (Mo.App.2000) *Colgan v. Wash. Realty Co.*, 879 S.W.2d 686, 689 (Mo.App.1994). "If [a plaintiff] cannot provide proof of all of the elements of ... negligent misrepresentation, a trial court may grant [a defendant's] motion for summary judgment on that count of the petition." *Id.*

*Dueker v. Gill*, --- S.W.3d ----, 2005 WL 2933319 (Mo.App. S.D.,Nov. 7, 2005).

At the time the representations regarding the tibial insert were made they were in fact accurate. Thus, plaintiffs have failed to establish the second element of

negligent misrepresentation, that through the failure to exercise reasonable care, the information was false.[5]

**Implied Warranties**

Defendants are entitled to summary judgment on plaintiffs' implied warranties of merchantability and fitness for a particular purpose because the insert was merchantable and fit for its particular purpose at the time of its sale in 1991. See, *Ragland Mills, Inc. v. General Motors Corp.*, 763 S.W. 2d 357, 360 (Mo App. 1989). Plaintiffs' reliance on *Matalunas v. Baker*, 569 S.W.2d 791, 794 (Mo.App. 1978), once again ignores the fact that the tibial insert was fit for it ordinary purpose at the time it was sold in 1991. No latent defect existed at the time of sale, rather the delamination occurred because of the length of time the insert sat on the shelf. The delamination is a consequence of the excessive shelf life and not a latent defect that existed at the time of sale.

**Exemplary Damages**

Because the record establishes that the product was not unreasonably dangerous at the time of sale and defendants are entitled to summary judgment on

[5] The fact that at the time of the sale the information was not misrepresented to plaintiffs does not, however, relieve defendant S & N of its duty to subsequently warn of the dangers of using a product that has a shelf life of longer than five years. Thus, it would appear that the issue of subsequent warnings would entail modification of any information previously distributed with the tibial inserts.

the strict liability claims, the claim for exemplary damages on these issues are moot. Defendants have not moved for summary judgment on plaintiffs' claim for exemplary damages on the negligent failure to warn claim, and as such this claim remains.

**Defendant Satterly's Motion for Summary Judgment**

The record clearly establishes that defendant Satterly had no knowledge of the dangers involved in placing this particular tibial insert into plaintiff Linda Stanger. As such, he was not a "learned intermediary" and therefore defendant S & N may not rely on this defense. Defendant S & N's argument that Satterly had constructive knowledge is unpersuasive. While information generally known by the medical profession may be considered, *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 672, this consideration is insufficient to overcome Satterly's testimony that he did not actually know of the danger. Defendant Satterly is entitled to summary judgment on plaintiffs' single claim against him that he was a "learned intermediary," and plaintiffs are entitled to summary judgment on the issue of whether defendants can utilize the learned intermediary defense.

**Conclusion**

Defendants are entitled to summary judgment on all of plaintiffs' claims with the exception of their negligent failure to warn of subsequent developments

regarding the shelf life of the tibial insert. Plaintiffs' motion for summary judgment as to this claim only is well taken. Defendant S&N's liability having been determined as to this issue, the trial in this matter shall be held on the remaining issue of damages as a result of S&N's failure to warn of the dangers inherent in using a tibial insert that had remained on the shelf longer than 5 years.

Accordingly,

**IT IS HEREBY ORDERED** that Defendants S&N, Toler Gross' Motions for Summary Judgment, [Doc. No.'s 97, 98 and 99] are granted in part and denied in part; plaintiffs' Motion for Partial Summary Judgment on their Strict Liability Product Defect Claim, [Doc. No. 113], is denied; plaintiffs' Motion for Summary Judgment on their Negligent Failure to Warn Claim, [Doc. No. 112], is granted; plaintiffs' Motion for Partial Summary Judgment on the Learned Intermediary Defense, [Doc. No. 90], is granted; and defendant Satterly's Motion for Summary Judgment, [Doc. 68], is granted.

Dated this 30th day of November, 2005.

HENRY EDWARD AUTREY
UNITED STATES DISTRICT JUDGE